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10/582,002	06/07/2006	Manabu Watanabe	Q95278	8934
23373 7590 02/03/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER CHOWDHURY, IQBAL HOSSAIN				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
02/03/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/582,002

Applicant(s)

WATANABE ET AL.

Examiner

IQBAL H. CHOWDHURY

Art Unit

1652

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 8-15, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-4 and 7-18 are currently pending.

In response to a previous Office action, a non-final action (mailed on July 15, 2009), Applicants filed a response and amendment on November 5, 2009, amending claims 7-9 and 16, and canceling claims 5-6 and 19-20 is acknowledged. Claims 1-4, 8-15 and 17-18 remain withdrawn as encompassing non-elected inventions.

Claims 7 and 16 are under consideration.

Applicants' arguments filed on November 5, 2009, have been fully considered but are not deemed persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicants' arguments regarding rejoinder issue is noted. Applicants have the right to rejoin invention directed to a method of using a product, when the product claims are allowed provided that applicants amend the methods claims to conform to the same scope as that of the allowed product claims. However, current claims of elected Group claims 7 and 16 are not allowable at this time. When claims 7 and 16 would be allowable; rejoinder request would be evaluated at that time.

Maintained-Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of claims 7 and 16 under 35 U.S.C. 112, first paragraph, on scope of enablement is maintained. This rejection has been discussed at length in the previous office action. The rejection is maintained as discussed previously in the previous office action and for the following reasons.

The specification while being enabling for a cellulase enzymes of SEQ ID NOs: 2, 4, 38 or 40 having endoglucanase activity, does not reasonably provide enablement for any protein from any source, which is 85% identical to the amino acid sequence of SEQ ID NO: 2, 4, 38, or 40 having endoglucanase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Arguments/Response:

Applicants argue that one skilled in the art would be enabled to make the presently claimed invention based upon the guidance provided by the disclosure in the specification and the common technical knowledge possessed by one skilled in the molecular biology arts. Nevertheless, and solely to advance prosecution of the present application, claims 5, 6, 19, and 20 have been canceled without prejudice. Accordingly, the rejection is rendered moot with regard to claims 5, 6, 19, and 20. In addition, claim 7 has been amended to delete "a modified protein comprising an amino acid sequence in which one or plural amino acids are deleted, substituted, inserted, or added in the amino acid sequence of SEQ ID NO: 2, 4, 38, or 40" and "whose reduction in the presence of

a surfactant is small", and to recite "(a) a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 38, or 40; and (b) a protein comprising an amino acid sequence having at least 85% identity to the amino acid sequence of SEQ ID NO: 2, 4, 38, or 40, and having an endoglucanase activity". Claim 16 has been amended to be dependent on claim 7. Applicants note that the Board of Appeals and Interferences in *Exparte Kubin* (BPAI 2007) has recognized that mere routine experimentation is required to enable the full scope of Applicants' claims reciting nucleic acids encoding proteins at least 80% identical to the disclosed amino acid sequence claimed. In the present case, the claimed protein has at least 85% sequence identity to the amino acid sequence of SEQ ID NO: 2, 4, 38, or 40 and having an endoglucanase activity.

Applicants arguments have been fully considered but are not deemed persuasive to overcome the rejection on scope of enablement issues. Claims still read on any polypeptide, which is 85% identical to the amino acid sequence of SEQ ID NO: 2, 4, 38 and 40 having endoglucanase activity, which is very broad because 15% non-identical proteins of SEQ ID NO: 2, 4, 38, or 40 (having about 44 amino acids are different out of about 300 amino acid protein) comprise many mutants, variants and recombinants, which may have endoglucanase activity or no activity. Thus, the scope of the claims is still not commensurate with the enablement provided by the disclosure with regard to the large number of proteins including mutants, variants and recombinants having endoglucanase activity or no activity broadly encompassed by the claims. In the instant case the disclosure is limited to the nucleotide and encoded amino acid sequence of only four proteins of SEQ ID NOs: 2, 4, 38 or 40.

Regarding the arguments about Kubin is not persuasive because the nucleic acid encoding protein of the Kuban and the instant application is completely different and the fact pattern are also not same, and thus, comparing a decision made by the Board for a particular product cannot be applicable for other product, when the product is completely different.

While methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants useful as cellulase requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the activity. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. For the rejected claims, this would clearly constitute **undue** experimentation. Guo et al. (Protein tolerance to random amino acid change, Proc Natl Acad Sci U S A, 2004 Jun 22; 101(25): 9205-10, Epub 2004 Jun 14) teach that the percentage of random single substitution mutations which inactivate a protein for the protein 3-methyladenine DNA glycosylase is 34% and that this number appears to be consistent with other studies in other proteins as well. Guo et al. further show in Table 1 that the percentage of active mutants for multiple mutants appears to be exponentially related to this by the simple formula $(.66)^x \times 100\%$ where x is the number of mutations introduced. Applying this estimate to the instant protein 85% identity allows up to 45 mutations within the 299 amino acids of SEQ ID NO: 40 and thus only $(.66)^{45} \times 100\%$ or $7.6 \times 10^{-7}\%$ (i.e. $\cong 1$ in 131 million) of random mutants having 85% identity would be active. Similarly at 95%

identity $1.9 \times 10^{-1}\%$ (1 in 509). Current techniques (i.e., high throughput mutagenesis and screening techniques) in the art would allow for finding a few active mutants within several hundred inactive mutants as is the case for the claims limited to 95% identity (despite even this being an enormous quantity of experimentation that would take a very long time to accomplish) but finding a few mutants within many millions or more as in the claims to 85% or less identity would not be possible. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification.

Sufficient guidance has **not** been provided in the instant specification or in the prior art as at best art teaches to avoid changes of 15% of the structure of SEQ ID NO: 1 but does little to suggest what changes would be successful particularly for those enzymes having the substantial number of alterations necessary to produce a protein having 85% identity to SEQ ID NO: 40.

Therefore, the rejection is maintained.

New-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmussen et al. (A cellulase preparation comprising an endoglucanase enzyme, WO 91/17243 A1, publication 11/14/1991, see IDS).

Rasmussen et al. teach a cellulase preparation comprising an endoglucanase enzyme and a gene encoding a cellulase enzyme which is 97.2% identical to the amino acid sequence of SEQ ID NO: 2 of the instant application. Rasmussen et al. also teach a vector comprising said nucleic acid encoding cellulase enzyme and a host cell transformed with said nucleic acid and a process for producing said cellulase enzyme in a transformed host cell (see abstract, p2, 21, Example 4 and claims 6-15).

Therefore, Rasmussen et al. anticipate claims 7 and 16 of the instant application as written.

Conclusion

Status of the claims:

Claims 1-4 and 7-18 are pending.

Claims 1-4, 8-15 and 17-18 are withdrawn.

Claims 7 and 16 are rejected.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, Patent Examiner
Art Unit 1652

/Andrew Wang/

Supervisory Patent Examiner, Art Unit 1652